

IN THE DRAWINGS

At the request of the Examiner, corrected replacement drawings are supplied herewith.

Enclosed is a complete set of formal drawings (Figs. 1-20B), including Replacement Sheets showing the following amendments to Figs. 19A-C and 20B: the term "Isatin sulfonic acid" was inserted into the y-axis label. Applicant submits that the specification states that the "Abundance" referred to on the y-axis of Figs. 19A-C and 20B is clearly the abundance of isatin sulfonic acid. See specification at page 14, lines 9-20. As described in the specification, the different peaks are isatin sulfonic acid molecular species with different masses (labeled 226, 228 and 230) that are due to the presence of 0, 2 or 4 heavy oxygen (¹⁸O) atoms on the isatin sulfonic acid molecule. This is further illustrated by FIG. 19A that identifies which of the isatin sulfonic acid species corresponds to the 226, 228 or 230 peak. Applicant submits that no new matter has been added to the specification.

REMARKS

This responds to the Office Action mailed on May 25, 2005, and the references cited therewith. Claims 1-44 are pending; claims 21-44 have been withdrawn from consideration by the Examiner in response to the requirement for restriction.

Claims 1, 2, 6, 10, 11, 12, 16 and 20 have been amended. Claims 1 and 11 now recite “an oxidized chemical probe.” Support for the language can be found throughout the application as originally filed, for example, at page 23, line 1 to page 24, line 8 and in the Examples. Claims 1 and 11 also recite the phrase “to thereby detect the immunological (inflammatory) response.” Support for the language can be found throughout the application as originally filed, for example, at page 4, line 2 to page 5, line 4; at page 19, line 22 to page 20, line 18 and the Examples. In addition, claims 1 and 11 recite the phrase “wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons. Support for the language can be found throughout the application as originally filed, for example, at page 18, lines 4 to 11, and in the Examples. Language relating to “any chemical species that possesses the chemical signature of ozone” has been removed from claims 6 and 12. An inadvertent typographical error (use of “spectrometry”) in claims 10 and 20 has been corrected by substitution with the term “chromatography.”

Applicant submits that no new matter has been added to the application.

§112 Rejection of the Claims

Claims 1-20 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner objects to certain phrases that are present in the claims. The issues relating to each term are discussed separately below.

Applicant reminds the Examiner that indefiniteness depends on whether one of skill in the art would understand the scope of the claim when the claim is read in light of the specification. *North American Vaccine Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 28 USPQ2d 1333 (Fed. Cir. 1993). If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Miles Laboratories Inc. v. Shandon, Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993).

Oxidation product of the chemical probe

The Examiner has rejected claims 1 and 11 for alleged indefiniteness of the phrase “oxidation product of the chemical probe.” According to the Examiner, it is unclear whether the oxidation product is an oxidized chemical probe or some other oxidation product. While Applicant believe the language is clear and definite as written, claims 1 and 11 now recite “an oxidized chemical probe.”

Applicant submits that the language of claims 1 and 11 is definite, and requests withdrawal of the rejection with respect to the language of claims 1 and 11.

Analyzing the sample for an oxidation product of the chemical probe

The Examiner has rejected claims 1 and 11 for alleged indefiniteness of the phrase “analyzing the sample for an oxidation product of the chemical probe.” According to the Examiner it is not clear how analyzing the sample for an oxidation product of the chemical probe amounts to the method for assaying for an immunological response, which is recited in the preamble.

While Applicant asserts that claims 1 and 11 are clear and definite as written, Claims 1 and 11 now include the phrase “to thereby detect the immunological [inflammatory] response” in order to expedite the prosecution of the claims.

Applicant submits that the language of claims 1 and 11 is definite, and requests withdrawal of the rejection with respect to the language of claims 1 and 11.

Reactive oxygen species

The Examiner has rejected claims 1, 4, 11 and 14 for alleged indefiniteness of the phrase “reactive oxygen species.” Claims 1 and 11 are now directed to assay methods “wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons.”

Applicant submits that the language of claims 1 and 11 is definite, and requests withdrawal of the rejection with respect to the language of claims 1 and 11.

Can be oxidized

The Examiner has rejected claims 2 and 12 for alleged indefiniteness of the phrase “can be oxidized.” According to the Examiner, it is not clear whether a step of oxidation is a required claim limitation.

Claims 2 and 12 are now drawn to “wherein the chemical probe is an alkene that can be oxidized during an immunological response in the mammal.” Applicant submits that this language is definite and reminds the Examiner that the method steps are defined by claims 1 and 11, from which claims 2 and 12 depend. No ambiguity exists as to the method because if the immunological/inflammatory response occurs the oxidized alkene is detected; and if no such immunological/inflammatory response occurs the oxidized alkene is not detected.

Applicant submits that the language of claims 2 and 12 is definite, and requests withdrawal of the rejection with respect to the language of claims 2 and 12.

Chemical signature of ozone

The Examiner has rejected claims 6 and 16 for alleged indefiniteness of the phrase “chemical signature of ozone.” Reference to chemical signature of ozone has been removed from claims 6 and 16. Applicant submits that the language of claims 6 and 16 is definite, and requests withdrawal of the rejection with respect to the language of claims 6 and 16.

Gas spectrometry

The Examiner has rejected claims 10 and 20 for alleged indefiniteness of the phrase “gas spectrometry.” Claims 10 and 20 are now directed to “gas chromatography.” Applicant submits that use of “gas spectrometry” was an inadvertent typographical error. Applicant submits that the language of claims 10 and 20 is definite, and requests withdrawal of the rejection with respect to the language of claims 10 and 20.

§102 Rejection of the Claims

Claims 1-20 were rejected under 35 U.S.C. § 102(b) for anticipation by Medford et al (U.S. Patent 5,846,959). According to the Examiner, Medford et al. describe a method for

assaying for an immunological response similar to the present methods. The Examiner cites Medford et al. at col. 4, lines 28-35, and lines 48-54 as allegedly disclosing the present methods.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, “it is only necessary for the patentee to show some tangible difference between the invention and the prior art.” *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

Claims 1 and 11 are directed to a method for assaying for an immunological response or an inflammatory response in a mammal comprising: (a) administering to the mammal a chemical probe for reactive oxygen species; (b) obtaining a sample from the mammal; and (c) analyzing the sample for an oxidized chemical probe to thereby detect the immunological or inflammatory response; wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons.

Medford et al. is limited to treatment of atherosclerosis. Nowhere does Medford et al. describe a method for detecting an immunological or inflammatory response. Applicant submits that such treatment methods are not a disclosure of detection methods. Hence, *inter alia* Medford et al. does not anticipate claims 1-20 because Medford et al. does not disclose the present detection methods.

The Examiner has alleged that Medford et al. discloses the present methods at col. 4, lines 28-36, which is reproduced below.

Screens for disorders mediated by VCAM-1 or a redox-sensitive gene are also provided that include the quantification of surrogate markers of the disease. In one embodiment, the level of oxidized polyunsaturated fatty acid, or other appropriate markers, in the tissue or blood, for example, of a host is evaluated as a means of assessing the "oxidative environment" of the host and the host's susceptibility to VCAM-1 or redox-sensitive gene mediated disease.

Applicant submits that this text from Medford et al. relates to screening for VCAM-1 or redox-sensitive gene disorders. This disclosure provides no disclosure or teaching on an immunological or inflammatory response. This disclosure also provides no disclosure or teaching on administering a chemical probe for a reactive oxygen species. Reference to the term "oxidative environment" is not a disclosure of a method for detecting an immunological or inflammatory response by administering a chemical probe for a reactive oxygen species.

With regard to the Examiner's allegations that col. 4, lines 48-54 of Medford et al. discloses a method for assaying an immunological response, Applicant fails to see how this text, which is recited below, discloses any such thing.

In another embodiment, in vivo models of atherosclerosis or other heart or inflammatory diseases that are mediated by VCAM-1 can be provided by administering to a host animal an excessive amount of PUFA or oxidized polyunsaturated fatty acid to induce disease. These animals can be used in clinical research to further the understanding of these disorders.

Applicant submits that mere mention of "inflammatory diseases" is not a disclosure of the present methods.

Moreover, to the extent that the Examiner is alleging that Medford et al. inherently discloses the invention, Applicant reminds the Examiner that an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. Here, no evidence establishes that the inherent feature (detecting an

immunological or inflammatory reaction by detecting reactive oxygen species) flows as a necessary conclusion from the Medford et al. disclosure.

Applicant requests withdrawal of this rejection under 35 U.S.C. § 102(b) because Medford et al. does not anticipate every element of claims 1-20.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (516) 795-6820 to facilitate prosecution of this application.

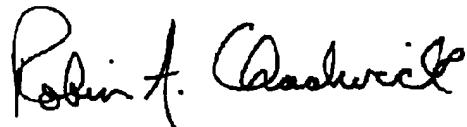
If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date October 24, 2005

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 25th day of October, 2005.

Name



Signature

